REMARKS/ARGUMENTS

Claims 2-6, and 18 are active. Claims 4 and 6 are amended to refer to the X-Ray diffraction patterns of the noted Figures as described in the application as originally filed.

Support for the amendments to Claims 18 is found on page 18, [0019].

No new matter is added.

The Examiner has maintained the Election of Species requirement and has indicated that the claims drawn to the elected species (Claim 4) is allowable. While Applicants appreciate that indication, Applicants again request that the claims not be restricted to the elected species as that election was for initial examination purposes only and that no prior art had been identified by the Office that would preclude expansion to the non-elected species. Thus, again, Applicants reiterate their request to expand consideration to all elected species.

To the new rejection that Claim 7 and 16-18, which define medicines comprising the specific polymorphs, are not enabled. The basis of the rejection is in short, based on an alleged unpredictability when a polymorph is processed into an medicinal composition, citing to the publication of Brittain.

Applicants respectfully disagree and provide the attached Rule 132 Declaration explaining why claim 18 presented here is enabled.

The significance of the present invention lies in the technological accomplishment that is the first success in isolating the crystal form of a sodium cyclohexanecarboxylate pentahydrate as described in this application. It has been found that this crystallized compound exhibits higher water-solubility, causes no substantial weight change despite moisture adsorption/desorption, and is excellent in long term storage stability (see [0005], Table 1 and FIG. 3 of the application).

As further evidenced by Table 3 and FIG. 5, the crystallized compounds, both Type-I crystals and Type-II crystals also are highly effective not only at water-solubility but also adsorption and desoprtion, compared to the free-type of the compound.

Moreover, the crystallized compound has the ability to maintain its crystallization continuously even when contained in a pharmaceutical preparation (e.g. capsule). Therefore, it is possible for a solid-type medicine to significantly improve in long term storage stability when containing such a crystal form of the compound.

An additional experiment has been performed demonstrating that the crystallized compounds as provided for in the claims of this application are capable of maintaining crystallization effectively as a component in a capsule.

Pattern (a) in Fig. 6 (attached to the Declaration) shows the powder X-ray diffractometry spectrum of the Type-II crystallized compound as provided in the claims. Pattern (b) in Fig. 6 shows the powder X-ray diffractometry spectrum of a capsule comprising the Type-II crystallized compound of the present invention and an additive agent. Pattern (c) in Fig. 6 shows the powder X-ray diffractometry spectrum of a capsule comprising a lactose monohydrate (which was used instead of the Type-II crystallized compound of the present invention) and an additive agent. The additive agent used in Pattern (b) is the same as that of the additive agent used in Pattern (c) with regard to their formulation and quantities.

The peak characteristic of the Type-II crystallized compound as provided in the claims has been found to become almost invisible at the region where the peaks derived from the additive agent make crossover, especially around 20°. In contrast, the other peaks characteristic of the Type-II crystallized compound have been clearly observed at the regions where there is no or little crossover of the peaks derived from the additive agent (e.g. 7.2°, 14.4°, 14.8°, 17.3° and 20.4°). From these data, it is evident that the Type-II crystallized

compound is significantly capable of maintaining the continued crystallization as a medicine, among others.

Therefore, formulating a crystalline compound as defined in the claims of the application into a medicinal composition that is the form of a tablet, powder, granule, and capsule would not have the issues that are identified in the Brittain publication cited by the U.S. patent office. Withdrawal of the rejection is requested.

A Notice of Allowance is requested.

Respectfully submitted,

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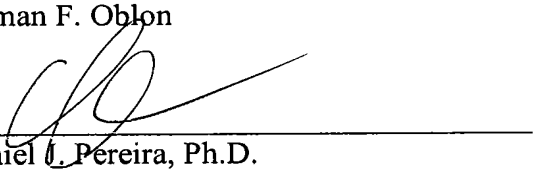

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